

Application No. : 10/655,532
Amdt. Dated : May 31, 2005
Reply To O.A. Of : March 28, 2005

REMARKS

By way of summary, Claims 42–73 are pending in this application. The pending claims have been rejected under §§ 112, 102, and 103. Applicants respectfully request reconsideration of the pending claims in light of the following comments.

35 U.S.C. § 112 Rejections

Claims 42, 45–69

The Office Action rejected Claims 42, and 45–69 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. In explaining the rejection, the Office Action stated that “[t]he phrase ‘alternately provided repeatedly’ in claims 42, 45–45, and 47, is a relative phrase which renders the claim indefinite.” Page 2. Applicants respectfully submit that the claims are not indefinite, as one of ordinary skill in the art would understand what is claimed, and as Applicants have explained below.

The specification states that “there is a need to deliver . . . agents directly to a treatment site to target the molecular events of the cell cycle in [smooth muscle cells].” Para. No. [0140]. This cycle is illustrated in Figure 26 as cell-cycle events 1114. The cells experiencing this cycle may be treated by a stent having a plurality of therapeutic agents alternately provided repeatedly thereon to treat the cells during the stages of the cycle, as described in the specification. In some embodiments, “an anti-inflammatory, such as Corticosteroids, is delivered first . . . followed by other agents in *repeated alternate cycles*” Para. No. [0142] (emphasis added). “In some embodiments, the other agents are *provided in a plurality of alternate cycles* for prolonged tissue drug concentrations.” Para. No. [0144] (emphasis added). The specification sets forth the following example of one embodiment of a stent with drug layers thereon that are alternately provided repeatedly:

[0147] In one preferred embodiment, the stent 1200 includes a first drug layer 1202, a second drug layer 1204, a third drug layer 1206, a fourth drug layer 1208 and a fifth drug layer 1210, each separated by a polymer barrier layer 1212, 1214, 1216, 1218, 1220 which may or may not include a drug. In one embodiment, the second drug layer 1204 and fourth drug

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layer 1208 comprise the same drug or type of drug, while the third drug layer 1206 and fifth drug layer 1210 comprise the same drug or type of drug. In one particularly preferred embodiment, the first drug layer 1202 comprises Corticosteroid, the second and fourth drug layers 1204, 1208 comprise Sirolimus (Rapamycin) and myclophenolic acid, and the third and fifth drug layers 1206, 1210 comprise Paclitaxel (Taxol). In some other embodiments, there may be additional alternating layers, such that the drugs are delivered cyclically.

Thus, Applicants respectfully submit that one of ordinary skill in the art would understand what is claimed and what would constitute infringement of the claims. For example, such an individual would understand that a stent having three therapeutic agents disposed thereon, and upon which the therapeutic agents are alternately provided repeatedly, infringes Claim 1 if one of the therapeutic agents is an anti-inflammatory. Therefore, Applicants respectfully submit that the pending claims particularly point out and distinctly claim the subject matter of the claims rejected under § 112, and respectfully request the withdrawal of these rejections.

Specification

The Specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Office Action states that there is no mention of the drugs that are alternately provided repeatedly. However, in Paragraph [0147] (recited above) is provided one example of drugs that are alternately provided repeatedly. Specifically, the drugs that are alternately provided repeatedly in Paragraph [0147] are Sirolimus in the second and fourth drug layers and Paclitaxel in the third and fifth drug layers. The specification, however, provides several other drugs that could be alternately provided repeatedly. The Applicants respectfully submit that the Specification does identify the drugs that are alternately provided repeatedly and does provide a proper antecedent basis for the claimed subject matter. Thus, Applicants respectfully request withdrawal of this objection.

Falotico Does Not Teach Every Element of Claims 42-43, 47-49, 53-57, 59, 61, 65-72

The Office Action rejected Claims 42-43, 47-49, 53-57, 59, 61, 65-72 under 35 U.S.C. § 102(e) as being anticipated by U.S. Publication No. 2003/0060877 to Falotico

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et al., and in the alternative under § 103(a) as rendered obvious by Falotico. Falotico does not anticipate the pending claims because the Falotico reference fails to identically teach or suggest every element of the claims. See M.P.E.P. § 2131 (stating that in order to anticipate a claim, a prior art reference must identically teach every element of the claim). Additionally, because Falotico fails to teach or suggest every element of the pending claims, Falotico does not render the pending claims obvious. See M.P.E.P. § 2143 (stating that in order to establish a *prima facie* case of obviousness for a claim, the prior art references must teach or suggest all the claim limitations). While Falotico does disclose a stent having multiple layers of drugs, Falotico does not teach or suggest, among other things, therapeutic agents alternately provided repeatedly on the stent.

The Office Action indicates that the limitation "alternately provided repeatedly" was being treated as a product by process limitation. The limitation should not be considered as such. In apparatus claims, the phrase "alternately provided repeatedly" is used to describe the structure of the layers of therapeutic agents disposed on the stent, not a product of some process that is being claimed. In method claims, the phrase is used to describe the manner in which the therapeutic agents are provided during the method of treatment.

Thus, Applicants respectfully submit that Falotico does not anticipate or render obvious the pending claims, and the anticipation and obviousness rejections of the claims based upon Falotico are respectfully requested to be withdrawn.

Rejections Under 35 U.S.C. § 103(a) Based On Falotico and Wnendt

The Office Action rejected various claims under 35 U.S.C. § 103 as being unpatentable over Falotico in view of U.S. Patent Publication No. 2004/0117008 by Wnendt et al. (the Wnendt reference). As discussed in the foregoing, the Falotico reference fails to teach, among other things, a stent having therapeutic agents alternately provided repeatedly. The Applicants submit that even if the Wnendt reference could be combined with the Falotico reference, the Wnendt reference also fails to teach or suggest a stent having therapeutic agents alternately provided

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repeatedly. Therefore, the Applicants respectfully submit that the combination of these references fails to teach or suggest the elements of the pending claims. See M.P.E.P. § 2143 (stating that in order to establish a *prima facie* case of obviousness for a claim, the prior art references must teach or suggest all the claim limitations).

Rejections Under 35 U.S.C. § 103(a) Based On Falotico and Palasis

The Office Action rejected various claims under 35 U.S.C. § 103 as being unpatentable over Falotico in view of U.S. Patent No. 6,369,039, issued to Palasis et al. As discussed in the foregoing, the Falotico reference fails to teach, among other things, a stent having therapeutic agents alternately provided repeatedly. The Applicants submit that even if the Palasis patent could be combined with the Falotico reference, the Palasis patent also fails to teach a stent having therapeutic agents alternately provided repeatedly. Therefore, the Applicants respectfully submit that the combination of these references fails to teach or suggest the elements of the pending claims.

Request For Telephone Interview

In view of the foregoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. If further issues remain to be resolved, the Applicants' attorney of record, Stephen C. Jensen, hereby formally requests a telephone interview with the Examiner. The Applicants' attorney can be reached at (949) 760-0404.

Respectfully submitted,

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